

REMARKS

Claims 1-56 are currently pending in the application and are addressed herein.

Election of Species

The Examiner contends that the present his application contains claims directed to the following patentably distinct species:

- 1) A method for selectively expressing a toxin in a cell comprising administering a DNA sequence as in claims 1-12, 25-40.
- 2) A method for selectively expressing a toxin in a cell comprising administering a messenger RNA sequence as in claims 13-24, 41-56.

The Examiner has required that the Applicant to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally found to be allowable. Currently, claims 1-56 are generic. Applicants hereby elect species 2 for prosecution on the merits.

In addition, Examiner has noted that claims 16 and 43 indicate that the messenger RNA sequence is administered "by administering an expression vector encoding the mRNA sequence". However, the Examiner contends that administering a messenger RNA (as in claims 13 and 41) does not encompass administering a vector encoding the messenger RNA. See, for example, U.S. Pat. Nos. 6,274,562, 6,107,028, 6,060,457, and 5,869,040 as examples of delivering RNA by expressing it from an expression vector. Therefore, the Examiner contends claims 16-24 and 43-56 are outside the scope of base claims 13 and 41, thus claims 16-24 and 43-56 are improper dependent claims.

Applicants respectfully contend that this dependency is not improper. Administering an expression vector encoding the mRNA sequence is merely another means of delivering (administering) the RNA. In these instances, the RNA to be administered is produced *in situ*

within the cell instead of being delivered pre-made into the cell. Claims 16-24 and 43-56 include all of the limitations of the base claims 13 and 41, yet add the further limitation that the RNA must be produced within the cell by a DNA construct delivered to the cell. Inherently, claims 16-24 and 43-56 must fall within the claim scope of the base claims 13 and 41 and, therefore, dependency is proper. However, for clarity's sake, Applicants have amended the claims to provide for better elucidation of the steps involved in creating the dependency.

Furthermore, the Examiner contends that the application contains claims directed to the following patentably distinct species of types of cancers: bladder, breast, cervical, colon, lung, prostate, and head and neck. Applicant respectfully traverse this requirement in that all claims are generic as they relate to the disclosed cancer species, as is well known in the art of cancer treatment methods.

However, in order to be fully responsive, Applicants elect lung cancer as a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 25-56 are generic.

Applicants understand that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicants' undersigned attorney has made a good faith effort to be responsive to the restriction requirement made in the Office Action dated June 21, 2006. If the Examiner would like to discuss the restriction requirement or to have Applicants provide any clarification of its terms, he is invited to contact Applicants' undersigned attorney at the phone number given below.

Application No. 10/718,163
Amendment Dated July 18, 2006
Reply to Official Action of June 21, 2006

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

ARRIGO DEBENEDETTI, et al.

By



Stephen R. Albainy-Jenei
Registration No. 41,487
Attorney for Applicant(s)
FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202
(513) 651-6823
salbainyjenei@fbtlaw.com